

## Interim analysis of a multi-center RSA study of a novel cementless total knee replacement

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**INTRODUCTION:** Cementless total knee arthroplasty (TKA) is increasing in popularity as a definitive treatment for end-stage osteoarthritis. Purported advantages to cementless TKA are shorter surgical time and improved long-term survivorship compared to cemented TKA. The purpose of this study is to determine the risk of aseptic loosening of a novel cementless TKA based on micromotion analysis of implants with respect to bone using radiostereometric analysis (RSA).

**METHODS:** Thirty patients requiring primary TKA were enrolled at two Canadian academic joint replacement centres. All patients received a porous CONCELOC tibial baseplate paired with a cruciate-retaining LEGION porous (n=24) or LEGION cemented (n=6) femoral component (Smith & Nephew, Memphis, TN). The patella was selectively resurfaced based on surgeon preference, and was resurfaced using either a cementless CONCELOC (n=10) or a cemented GENESIS inset biconvex patella (n=6). During surgery, RSA beads were inserted into the tibia, femur, and patella (when a cementless CONCELOC patellar implant was employed). Patients received supine RSA imaging at six weeks (baseline), and six and 12 months following surgery. The primary study outcome was change in maximum total point motion (MTPM) of the tibial baseplate between six and 12 months. A secondary outcome was to characterize migration patterns of the tibial baseplate over the follow-up period. Patient reported outcome measures (PROMs) from pre-operative to post-operative time points using Oxford-12 Knee Score (OKS), European Quality of Life (EQ-5D), Forgotten Joint Score (FJS), and visual analogue scale (VAS) for satisfaction with surgery were also collected.

**RESULTS:** At the time of submission, 30 patients (16 females) completed six-month follow-up and 13 patients (seven females) had completed 12 month follow-up. Our patient cohort had a mean age at surgery of 66 years (range: 53-79) and a mean body mass index of 30.6 kg/m<sup>2</sup> (standard deviation: 3.8). Change in MTPM between six and 12 months was 0.09mm for 13 patients. Mean tibial baseplate MTPM at six and 12 months was 1.22mm (SD: 0.94) and 1.31mm (SD: 0.65), respectively. The pattern and magnitude of baseplate migration remained constant between six and 12 months (Figure 1), indicating stability of fixation. Patients reported substantial improvement in functional (OKS, FJS) and health-related (EQ-5D) PROMs following surgery. Patients reported 83.8% and 85.0% satisfaction VAS at six and 12 months, respectively.

**DISCUSSION:** This study provides valuable early data on the fixation of this novel cementless TKA implant. Based on the available data, implant migration patterns for this patient cohort did not indicate any concerns for future aseptic loosening. Follow-up is on-going and further analysis will be performed to confirm this finding at 24 months post-operatively.

**CLINICAL RELEVANCE:** This study examines the early post-operative migration of a novel cementless tibial baseplate using RSA. Implant migration primarily occurred early and stabilized between the six and 12 month follow-up intervals and therefore did not indicate any concerns for future aseptic loosening.

### IMAGES AND TABLES:

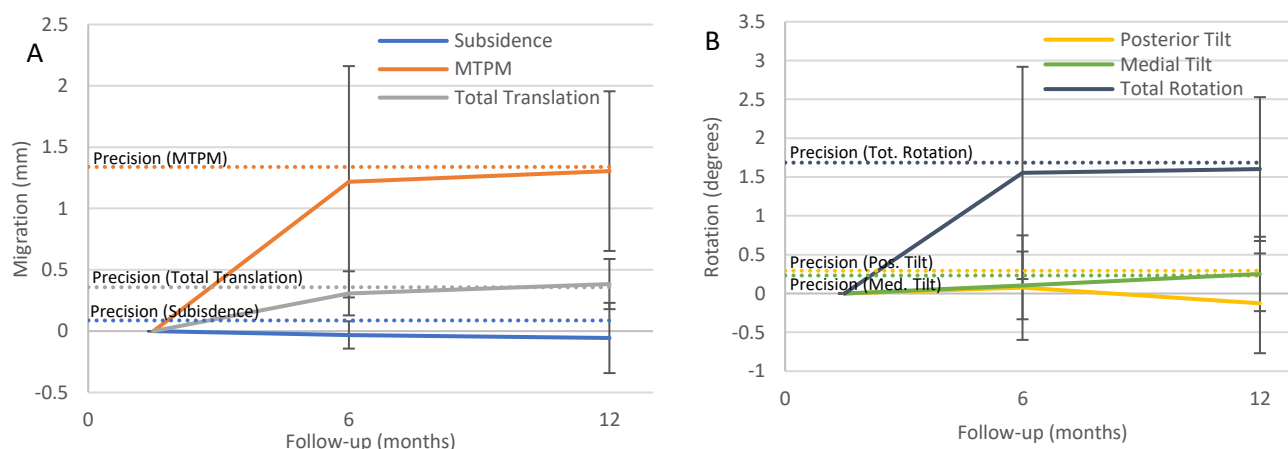


Figure 1. A) Tibial baseplate translation up to 12 months. B) Tibial baseplate rotation up to 12 months. Error bars indicate 1 standard deviation. Precision (dashed) lines represent the mean + standard deviation (bias and precision) of double examinations obtained at 6 weeks.